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Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

JEFFREY W. MOEHLENBRUCK  
JOHN P. RANIERI

Serial No.: Unknown

Filed: Concurrently Herewith

For: METHODS AND COMPOSITIONS FOR  
TREATING INTERVERTEBRAL DISC  
DEGENERATION

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: SBI-064-DIV

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This application is a divisional application of Serial No. 09/545,441, filed April 7, 2000, and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/545,441.

The present Information Disclosure Statement is being filed within three months of the filing date of this patent application or prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Director is hereby authorized to deduct said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/2103.013882.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,

WILLIAMS, MORGAN & AMERSON  
CUSTOMER NO. 23720

Date: March 29, 2004



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AGENT FOR APPLICANT

Form PTO-1449 (modified)		Atty. Docket No. SBI-064-DIV	Serial No. Unknown
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Jeffrey W. Moehlenbruck and John P. Ranieri	
		Filing Date: Concurrently Herewith	Group: Unknown
U.S. Patent Documents <i>See Pages 1-4</i>	Foreign Patent Documents <i>See Page 4</i>	Other Art <i>See Pages 4-8</i>	

**U.S. Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	6,419,702	07-2002	Ferree	623	17.11	
	A2	6,352,557	03-2002	Ferree	623	17.11	
	A3	6,344,058	02-2002	Ferree	623	17.11	
	A4	6,340,369	01-2002	Ferree	623	17.11	
	A5	6,290,692	09-2001	Klima <i>et al.</i>	604	524	
	A6	6,273,876	08-2001	Klima <i>et al.</i>	604	264	
	A7	6,245,107	06-2001	Ferree	623	17	
	A8	6,203,732	03-2001	Clubb <i>et al.</i>	264	81	
	A9	6,132,461	10-2001	Thompson	623	1.15	
	A10	6,132,460	10-2001	Thompson	623	1.15	
	A11	6,110,164	08-2000	Vidlund	604	542	
	A12	6,107,004	08-2000	Donadio III	430	320	
	A13	6,080,579	06-2000	Hanley Jr. <i>et al.</i>	435	366	
	A14	6,051,648	04-2000	Rhee <i>et al.</i>	525	54.1	
	A15	6,033,394	03-2000	Vidlund <i>et al.</i>	604	524	
	A16	6,027,863	02-2000	Donadio III	430	320	
	A17	6,024,754	02-2000	Engelson	606	213	
	A18	6,022,343	02-2000	Johnson <i>et al.</i>	604	526	
	A19	5,976,186	11-1999	Bao <i>et al.</i>	623	17	
	A20	5,976,174	11-1999	Ruiz	606	213	
	A21	5,964,807	10-1999	Gan <i>et al.</i>	623	17	
	A22	5,962,325	10-1999	Naughton <i>et al.</i>	435	395	

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	A23	5,944,754	08-1999	Vacanti	623	11	
	A24	5,919,235	07-1999	Husson <i>et al.</i>	623	17	
	A25	5,916,225	06-1999	Kugel	606	151	
	A26	5,911,752	06-1999	Dustrude <i>et al.</i>	623	1	
	A27	5,879,366	03-1999	Shaw <i>et al.</i>	606	213	
	A28	5,874,397	02-1999	Schimmel <i>et al.</i>	510	531	
	A29	5,865,846	02-1999	Bryan <i>et al.</i>	623	17	
	A30	5,854,397	12-1998	Mechanic	520	356	
	A31	5,827,328	10-1998	Buttermann	623	17	
	A32	5,827,325	10-1998	Buttermann	623	17	
	A33	5,824,093	10-1998	Ray <i>et al.</i>	623	17	
	A34	5,817,153	10-1998	Pendl <i>et al.</i>	8	94.11	
	A35	5,815,904	10-1998	Clubb <i>et al.</i>	29	418	
	A36	5,800,550	09-1998	Sertich	623	17	
	A37	5,800,549	09-1998	Bao <i>et al.</i>	623	17	
	A38	5,800,537	09-1998	Bell	623	11	
	A39	5,795,353	08-1998	Felt	623	18	
	A40	5,776,142	07-1998	Gunderson	606	108	
	A41	5,741,429	04-1998	Donadio	615	8	
	A42	5,733,337	03-1998	Carr Jr. <i>et al.</i>	623	11	
	A43	5,716,416	02-1998	Lin	623	17	
	A44	5,681,310	10-1997	Yuam <i>et al.</i>	606	61	

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	A45	5,645,597	07-1997	Krapiva	623	17	
	A46	5,573,520	11-1996	Schwartz <i>et al.</i>	604	282	
	A47	5,562,736	10-1996	Ray <i>et al.</i>	623	17	
	A48	5,545,229	08-1996	Parsons <i>et al.</i>	623	17	
	A49	5,540,715	07-1996	Katsaros <i>et al.</i>	606	213	
	A50	5,514,180	05-1996	Heggeness <i>et al.</i>	623	17	
	A51	5,478,739	12-1995	Slivka <i>et al.</i>	435	240.23	
	A52	5,464,439	11-1995	Gendler	623	16	
	A53	5,437,288	08-1995	Schwartz <i>et al.</i>	128	772	
	A54	5,425,772	06-1995	Brantigan	623	17	
	A55	5,390,683	02-1995	Pisharodi	128	898	
	A56	5,370,660	12-1994	Weinstein <i>et al.</i>	606	215	
	A57	5,342,394	08-1994	Matsuno <i>et al.</i>	606	213	
	A58	5,314,477	05-1994	Marnay	623	17	
	A59	5,304,194	04-1994	Chee <i>et al.</i>	606	191	
	A60	5,259,043	11-1993	Stone	623	66	
	A61	5,258,043	11-1993	Stone	623	66	
	A62	5,192,326	03-1993	Bao <i>et al.</i>	623	17	
	A63	5,171,278	12-1992	Pisharodi	623	17	
	A64	5,147,374	09-1992	Fernandez	606	151	
	A65	5,108,438	04-1992	Stone	623	17	
	A66	5,100,422	03-1992	Berguer <i>et al.</i>	606	151	

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	A67	5,047,055	09-1991	Bao <i>et al.</i>	623	17	
	A68	5,015,255	05-1991	Kuslich	623	17	
	A69	4,932,696	06-1990	White	292	336.3	
	A70	4,904,260	02-1990	Ray <i>et al.</i>	623	17	
	A71	4,834,757	05-1989	Brantigan	623	17	
	A72	4,801,299	01-1989	Brendel <i>et al.</i>	623	1	
	A73	4,772,287	09-1988	Ray <i>et al.</i>	623	17	
	A74	4,663,358	05-1987	Hyon <i>et al.</i>	521	64	
	A75	4,413,359	11-1983	Akiama <i>et al.</i>	3	1	

**Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	EP 0411925 A2	08-1990	Europe	C08H	1/06	Yes
	B2	WO 91/16867	05-1991	PCT	A61F	2/44	Yes
	B3	WO 94/25080	04-1994	PCT	A61L	27/00	Yes
	B4	WO 00/62832	04-2000	PCT	A61L	27/16	Yes
	B5	WO 00/15274	03-2000	PCT	A61L	27/36	Yes

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C1	Aguiar <i>et al.</i> , "Notochordal Cells Interact with Nucleus Pulposus Cells: Regulation of Proteoglycan Synthesis," <i>Exp. Cell Res.</i> , 246:129-37, 1999.

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	C2	Ahlgren <i>et al.</i> , "Effect of Anular Repair on the Healing Strength of the Intervertebral Disc: A Sheep Model," <i>Spine</i> , 25:2165-70, 2000.
	C3	Antoniou <i>et al.</i> , "The Human Lumbar Endplate: Evidence of Changes in Biosynthesis and Denaturation of the Extracellular Matrix With Growth, Maturation, Aging, and Degeneration," <i>Spine</i> , 21:1153-61, 1996.
	C4	Antoniou <i>et al.</i> , "The Human Lumbar Intervertebral Disc: Evidence for Changes in the Biosynthesis and Denaturation of the Extracellular Matrix with Growth, Maturation, Aging and Degeneration," <i>J. Clin. Invest.</i> , 98:996-1003, 1996.
	C5	Ariga <i>et al.</i> , "The Relationship Between Apoptosis of Endplate Chondrocytes and Aging and Degeneration of the Intervertebral Disc," <i>Spine</i> , 26:2414-20, 2001.
	C6	Bao <i>et al.</i> , "The artificial disc: theory, design and materials," <i>Biomaterials</i> , 17:1157-67, 1996.
	C7	Buckwalter, "Spine Update: Aging and Degeneration of the Human Intervertebral Disc," <i>Spine</i> , 20:1307-14, 1995.
	C8	Chelberg <i>et al.</i> , "Identification of heterogeneous cell populations in normal human intervertebral disc," <i>J. Anat.</i> , 186:43-53, 1995.
	C9	Chiba <i>et al.</i> , "A New Culture System to Study the Metabolism of the Intervertebral Disc <i>In Vitro</i> ," <i>Spine</i> , 23:1821-27, 1998.
	C10	Cinotti <i>et al.</i> , "Results of Disc Prosthesis After a Minimum Follow-up Period of 2 Years," <i>Spine</i> , 21:995-1000, 1996.
	C11	Duance, "Changes in Collagen Cross-Linking in Degenerative Disc Disease and Scoliosis," <i>Spine</i> , 23:2545-51, 1998.
	C12	Enker <i>et al.</i> , "Artificial Disc Replacement: Preliminary Report with a 3-year Minimum Follow-up," <i>Spine</i> , 18:1061-70, 1993.
	C13	Frick <i>et al.</i> , "Lumbar Intervertebral Disc Transfer: A Canine Study," <i>Spine</i> , 19:1826-34, 1994.
	C14	Griffith <i>et al.</i> , "A Multicenter Retrospective Study of the Clinical Results of the LINK SB Charite Intervertebral Prosthesis: The Initial European Experience," <i>Spine</i> , 19:1842-49, 1994.
	C15	Gruber, "Anti-Apoptotic Effects of IGF-1 and PDGF on Human Intervertebral Disc Cells <i>In Vitro</i> ," <i>Spine</i> , 25:2153-57, 2000.

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**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C16	Gu <i>et al.</i> , "The Anisotropic Hydraulic Permeability of Human Lumbar Anulus Fibrosus: Influence of Age, Degeneration, Direction, and Water Content," <i>Spine</i> , 24:2449-55, 1999.
	C17	Hadjipavlou <i>et al.</i> , "The Effect of Chymopapain on Low Back Pain," <i>Orthopedic Review</i> , 21:733-38, 1992.
	C18	Horner <i>et al.</i> , "2001 Volvo Award Winner in Basic Science Studies: Effect of Nutrient Supply on the Viability of Cells From the Nucleus Pulposus of the Intervertebral Disc," <i>Spine</i> , 26:2543-49, 2001.
	C19	Jahnke <i>et al.</i> , "Proteoglycans of the Human Intervertebral disc: Electrophoretic heterogeneity of the Aggregating Proteoglycans of the Nucleus Pulposus," <i>Biochem. J.</i> , 251:347-56, 1988.
	C20	Kappa <i>et al.</i> , "Collagen Synthesis and Types I, II, IV, and VI Collagens in an Animal Model of Disc Degeneration," <i>Spine</i> , 20:59-67, 1995.
	C21	Kawakami <i>et al.</i> , "Pathomechanism of Pain-Related Behavior Produced by Allografts of Intervertebral Disc in the Rat," <i>Spine</i> , 21:2101-07, 1996.
	C22	Lee <i>et al.</i> , "New Use of a Three Dimensional Pellet Culture System for Human Intervertebral Disc Cells: Initial Characterization and Potential Use of Tissue Engineering," <i>Spine</i> , 26:2316-22, 2001.
	C23	Madawi <i>et al.</i> , "Biocompatible Osteoconductive Polymer Versus Iliac Graft: A Prospective Comparative Study for the Evaluation of Fusion Pattern After Anterior Cervical Discectomy," <i>Spine</i> , 21:2123-29, 1996.
	C24	Martz <i>et al.</i> , "Materials and Design of Spinal Implants – A Review," <i>Applied Biomaterials</i> , pp. 267-88, Sept. 1997.
	C25	Matsuzaki <i>et al.</i> , "Allografting Intervertebral Discs in Dogs: A Possible Clinical Application," <i>Spine</i> , 21:178-83, 1996.
	C26	Meade <i>et al.</i> , "Immunogenicity of Collagenous Implants," <i>Biomaterials</i> , 11:176-80, 1990.
	C27	Melrose <i>et al.</i> , "Proteoglycan Heterogeneity in the Normal Adult Ovine Intervertebral Disc," <i>Matrix Biology</i> , 14:61-75, 1994.
	C28	Moore <i>et al.</i> , "Biocompatibility and Immunologic Properties of Pericardial Tissue Stabilized by Dye-Mediated Photooxidation," <i>J. Heart Valve Dis.</i> , 6:307-15, 1997.

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	C29	Nehrer <i>et al.</i> , "Matrix Collagen Type and Pore Size Influence Behavior of Seeded Canine Chondrocytes," <i>Biomaterials</i> , 18:769-76, 1997.
	C30	Nishida <i>et al.</i> , "Adenovirus-Mediated Gene Transfer to Nucleus Pulposus Cells," <i>Spine</i> , 23:2437-42, 1998.
	C31	Nishida <i>et al.</i> , "Modulation of the Biologic Activity of the Rabbit Intervertebral Disc by Gene Therapy: an <i>In Vitro</i> Study of Adenovirus-Mediated Transfer of the Human Transforming Growth Factor $\beta$ 1 Encoding Gene," <i>Spine</i> , 24:2419-25, 1999.
	C32	Nishimura <i>et al.</i> , "Percutaneous Reinsertion of the Nucleus Pulposus: An Experimental Study," <i>Spine</i> , 23:1531-38, 1998.
	C33	Oegema <i>et al.</i> , "Aggregated Proteoglycan Synthesis in Organ Cultures of Human Nucleus Pulposus," <i>J. Biol. Chem.</i> , 254:10579-81, 1979.
	C34	Okuma <i>et al.</i> , "Reinsertion of Stimulated Nucleus Pulposus Cells Retards Intervertebral Disc Degeneration: an <i>In Vitro</i> Experimental Study," <i>J. Orthopedic Research</i> , 18:988-97, 2000.
	C35	Olmarker <i>et al.</i> , "Ultrastructural Changes in Spinal Nerve Roots Induced by Autologous Nucleus Pulposus," <i>Spine</i> , 21:411-14, 1996.
	C36	Pokharna <i>et al.</i> , "Collagen Crosslinks in Human Lumbar Intervertebral Disc Aging," <i>Spine</i> , 23:1645-48, 1998.
	C37	Roberts <i>et al.</i> , "Transport Properties of the Human Cartilage Endplate in Relation to its Composition and Calcification," <i>Spine</i> , 21:415-20, 1996.
	C38	Sasaki <i>et al.</i> , "Effects of Chondroitinase ABC on Intradiscal Pressure in Sheep: an <i>In Vitro</i> Study," <i>Spine</i> , 26:463-68, 2001.
	C39	Schollmeier <i>et al.</i> , "Observations on Fiber-Forming Collagens in the Anulus Fibrosus," <i>Spine</i> , 25:2736-41, 2000.
	C40	Skaggs <i>et al.</i> , "Regional Variation in Tensile Properties and Biochemical Composition of the Human Lumbar Anulus Fibrosus," <i>Spine</i> , 19:1310-19, 1994.
	C41	Stevens <i>et al.</i> , "Biological Changes in the Annulus Fibrosus in Patients with Low-Back Pain," <i>Spine</i> , 7:223-33, 1982.

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	C42	Sumida <i>et al.</i> , "Serial Changes in the Rate of Proteoglycan Synthesis After Chemonucleolysis of Rabbit Intervertebral Discs," <i>Spine</i> , 24:1066-70, 1999.
	C43	Urban <i>et al.</i> , "Chemistry of the Intervertebral Disc in Relation to Functional Requirements," <i>Grieves Modern Manual Therapy</i> , pp. 163-75, 1994.
	C44	Wehling <i>et al.</i> , "Transfer of Genes to Chondrocytic Cells of the Lumbar Spine: Proposal for a Treatment Strategy of Spinal Disorders by Local Gene Therapy," <i>Spine</i> , 22:1092-97, 1997.
	C45	Wittenberg <i>et al.</i> , "Five-Year Results From Chemonucleolysis With Chymopapain or Collagenase: A Prospective Randomized Study," <i>Spine</i> , 26:1835-41, 2001.

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